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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,492	03/06/2002	Elizabeth S. Light	142/003/PCT	8768

23874 7590 07/28/2005

VENTANA MEDICAL SYSTEMS, INC.
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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/582,492	Applicant(s) LIGHT ET AL.	
	Examiner Juliet C. Switzer	Art Unit 1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3,7,17,19 and 22*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

JULIET C. SWITZER
PRIMARY EXAMINER
7/25/05

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant traverses the 102 rejection arguing that the oligonucleotide primers taught by Meijer et al. are not "a plurality of genomic HPV DNA probe sets." This is not persuasive because there is no strucutral limitaiton in the claim that differentiates the probes taught by Meijer et al. from those claimed. The nucleic acids used by Meijer et al. are indeed found within the genome of the target HPV, and thuse they are comprised of "genomic" DNA. The probe sets taught by Meijer et al. would hybridize to a full length genomic sequence of HPV, as well as to a fragmented sequence. It is acknowledged that the probe sets would to only a small portion of the full length genome of the HPV isolate, but there is no structural or even functional limtation in the claims to require that the probe sets hybridize to each section of the HPV genome. Applicant refers to a statement in the specificaiton that the inventive probes "are not similar to oligonucleotide probes as used in the prior art" but this portion of the specification does not provide structure for the instant claims. Further, this is not a limiting definition, and although the claims are interpreted in light of the specificaiton, limitations from the specificaiton are not read into the claims. The claims must be given their broadest reasonable interpretation. The rejection is maintained. Applicant's arguments regarding the 103 rejections under Miejer et al. in veiw of Orth et al. or Bauer et al. rely on the same distinction between the oligonucleotide probes taught by Miejer et al. and the probes disclosed in the instant invention. The arguments are not persuaisve for the same reasons as the arguments are not persuasive to overcome the 102 rejection.

Upon entry of the amendment, claims 1, 3, 17 and 19 remain rejected in view of Nuovo et al. in view of Cox et al.

Applicant traverses the rejection beginning on page 9 of the response.
The remarks on pages 9-10 summarize the examiner's position. At page 11, applicant's argue that the rejection employes the use of improper hindsight reasoning to combine the references. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant points out that Nuovo et al. discuss the use kits that would detect a variety of HPV isolates including low-risk HPV types. Applicant concludes therefore, that these kits cannot be used to establish obviousness of the claimed invention. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Even still, as the rejection discusses, Nuovo et al. also provide kits that hybridize to only subsets of HPV types- specifically Digene kits that would detect only hpv 16 and 18 or a mix that would detect only HPV 31, 33, and 35. The rejection specifically refers to these kits. A reference must be considered for all that it would provide to the skilled practitioner. In this case Nuovo et al. specifically provide mixes that would detect only subsets of the HPV isolates that are detected by the Omniprobe.

Aplicants argue that even a type specific probe set for both 16 and 18 would not detectably hybridize to essentially the full length genomic sequences of HPV types 33, 35, and 51. It is noted however, that applicant's specification at Table 1 appears to dispute this assertion since it shows that one of these two probes detects these HPV types at a low level- that is at the "barely detectable" level at least under the experimental conditions utilized in the specification. Nonetheless, the rejection does not rely on this property, but goes on to address why one would probe sets that include fragments of each of the genomes listed in claim 1.

Applicant argues that the examiner uses improper hindsight reasoning to combine Nuovo et al. with Cox et al. The examiner disagrees. Nuovo et al. teach a variety of different mixtures of probes that wer made "using the entire genome" of HPV isolates. Cox et al. provides a cocktail that contains therein full length genomic probes to only high risk types 16, 18, 31, 33, 35 and 51, and regarding claim 3, 45, 52, and 56, further suggesting the inclusion of types 39 and 58. Thus they exemplify the use of a cocktail for the detection of high risk HPV, albiet for different method than that used by Nuovo. As the rejection sets forth, the examiner maintains that one would have been motivated to include additional probes in the mixes provided by Nuovo et al. following the guidance of Cox et al. in order to provide a single mx that would detect many different known high risk HPV types. Regardless of the methodology used by Cox et al., they provide the clear suggestion to provide mixes of HPV probes for the detection of high risk HPV types.

Thus, even if the amendments to the claims are entered, all of the rejections of record are MAINTAINED.